



NOV - 7 1997

0820 '97 DEC 16 P1:44

Mr. Rakesh M. Amin
Dilling and Dilling
150 North Wacker Drive
Chicago, Illinois 60606

Dear Mr. Amin:

This is in response to your letter of October 20, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act), on behalf of Vitality Corporation, Carson City, Nevada. Your submission states that Vitality Corporation is making, among other claims, the following claims for the product "Angio-Clear:"

"Vitamin C plays a role in increasing collagen that helps protect blood vessels and may reduce levels of lipoprotein(a)"

"L-Lysine aides in preventing the development of lipoprotein(a)"

"L-Proline helps aid in the maintenance and repair of artery lining"

Section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, cure, or mitigate disease, namely, coronary artery disease by reducing the level of a blood-borne substance that is associated with increased risk of coronary artery disease and repairing arterial vessels damaged by coronary artery disease. In addition, the name of the product (Angio-Clear) suggests that the product is intended to treat, cure, prevent, or mitigate disease by treating or preventing plaque formation (i.e., the lesions characteristic of coronary artery disease). These claims do not meet the requirements of section 403(r)(6) of the act. These claims suggest that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, and that it is subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, San Francisco District Office, Office of Compliance, HFR-PA140

claim?

DILLING AND DILLING
ATTORNEYS AT LAW
150 NORTH WACKER DRIVE
CHICAGO, ILLINOIS 60606
(312) 236-8417

RECEIVED
OCT 23 1997

KIRKPATRICK W. DILLING
KAREN A. WEAVER, R.PH.
RAKESH M. AMIN, R. PH.

ESTABLISHED 1917

ALBERT W. DILLING

1892 - 1969

JOHN M. MANN

PATENT AND TRADEMARK
COUNSEL

October 20, 1997 ⁰⁸²¹ '97 DEC 16 P1:44

Office of Special Nutritionals (HFS-450)
Center for Food Safety and
Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

Via Overnight Delivery

Re: Notification of Statements of Nutritional Support

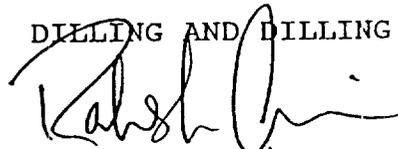
Dear Sir:

Enclosed is the original and two copies of an executed notification of Statements of Nutritional Support as required under Section 101.93 of 21 Code of Federal Regulations.

If necessary, please address future correspondence to our firm.

Sincerely yours,

DILLING AND DILLING



Rakesh M. Amin

Enclosure

75560 CALLE DEL SUR
INDIAN WELLS, CALIFORNIA 92210
(619) 568-1924
TELEFAX No.
(619) 341-1045

CALIFORNIA LEGAL ASSOCIATE
R. CHANDLER MYERS
301 NORTH LAKE AVENUE
PASADENA, 91101
(818) 792-0007



55372
TELEFAX No.
(312) 236-8418
CABLE ADDRESS
DILORON

Office of Special Nutritionals (HFS-450)
Food and Drug Administration

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October 20, 1997

<u>Statement Text</u>	<u>Name of Subject Dietary Ingredient(s)</u>	<u>Brand Name</u>
5) "Helps provide nutritional support for the Eyes and Vision".	Vitamin A, Vitamin D, Vitamin E, Vitamin C, Vitamin B-1, Vitamin B-2, Niacin, Vitamin B-6, Pantothenic Acid, Calcium, Magnesium and Zinc	Vision
6) "Calcium and magnesium work together to maintain healthy bones and teeth"; "Magnesium is involved in energy generation"; and "Vitamin D is essential for calcium assimilation and utilization".	Calcium, Magnesium and Phosphorus	Calcium- Magnesium

The information contained in this notice is complete and accurate. The above distributor has substantiation that the statements are truthful and not misleading.



Gary Paulsen
President
Vitality Corporation